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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/764,373	01/23/2004	Arnold Stan Lippa	10596-017-999	9971
20583	7590	01/23/2006	EXAMINER	
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			SOLOLA, TAOFIQ A	
			ART UNIT	PAPER NUMBER
			1626	
DATE MAILED: 01/23/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/764,373	<b>Applicant(s)</b> LIPPA ET AL.	
	<b>Examiner</b> Taofiq A. Solola	<b>Art Unit</b> 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☐ Claim(s) 24,26-29,31-44 and 49-52 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 24,26-29,31-44 and 49-52 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date: ____ | 6) <input type="checkbox"/> Other: ____.  |

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Claims 24, 26-29, 31-44, 49-52 are pending in this application.

Claims 1-23, 25, 30, 45-48, 53-56 are cancelled.

### ***Request for Continued Examination***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.117(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/16/05 has been entered.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 24, 26-29, 31-44, 49-52 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating the diseases listed in the claims, does not reasonably provide enablement for preventing the diseases. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. The claimed methods of use are not believable.

For rejection under 35 U.S.C. 112, first paragraph, the following factors must be considered (In re Wands, 8 USPQ2d 1400, 1404 (CAFC, 1988):

- 1) Breadth of claims.
- 2) Nature of invention.

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- 3) State of prior art.
- 4) Level of ordinary skill in the art.
- 5) Level predictability in the art.
- 6) Amount of direction and guidance provided by the inventor.
- 7) Existence of working examples.
- 8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The breath of the claimed invention involves medicinal chemistry. The nature of the invention is in the field of using the compound for preventing the listed disorders due to dopamine reuptake inhibition. The state of the prior art is what prior art knows about the nature of the invention. There is no known prior art claiming the use of the compound for preventing the various disorders arising from dopamine reuptake inhibition. The level of ordinary skill in the art is high but only in treating the listed disorders. See US 6,204,284. The predictability or lack thereof in the art refers to the ability of one skilled in the art to extrapolate the disclosed or known results to the claimed invention. The lower the predictability, the higher the direction and guidance that must be provided by applicant. In the instant invention the predictability is very low and consequently, the need for higher levels of direction and guidance by applicant. However, the amount of direction and guidance provided by applicant is limited to assay on the affinity of the instant compound for dopamine receptor site. There is no evidence in the specification that established correlation between applicant's experiment and prevention of the various disorders. See Ex parte Mass, 9 USPQ2d 1746, 1987. Therefore, the quantity of experimentation required to use the compound as claimed, based on applicant's limited disclosure would be undue burden because, one of ordinary skill in the art would have to

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perform significant amount of experiments. By deleting "preventing" from claims 24, 31, 35, 39, 42, 49, 52, the rejection would be overcome.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 24, 26-29, 31-44, 49-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beer et al., US 6,204,284 B1.

Applicant claims a method of using the instant compound for treating various disorders by inhibition of dopamine reuptake. The compound is in its (-) isomeric form substantially free of the corresponding (+) enantiomer.

#### **Determination of the scope and content of the prior art (MPEP §2141.01)**

Beer et al., teach a method of using the racemic mixture of the instant compound for treating disorders by inhibition of dopamine reuptake. Such disorders are chemical abuse, eating disorders: obesity, and compulsive behaviors.

#### **Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)**

The difference between the instant invention and that of Beer et al., is that applicant uses the (-) isomer substantially free of the corresponding enantiomer instead of racemic mixture by Beer et al. Also, applicant claims treatment of specific compulsive disorders instead of generic compulsive disorders by Beer et al.

#### **Finding of prima facie obviousness--rational and motivation (MPEP §2142.2413)**

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The term "compulsive disorders" embraces the specific compulsive disorders by applicant. The racemic mixture of Beer et al., include the (-) isomer and the phraseology "substantially free" implies the instant compound is not 100 % (-) isomers. The compound of Beer et al., and the instant compound have both isomers except in degrees. Therefore, the instant invention is prima facie obvious from the teaching of Beer et al. One of ordinary skill in the art would have known to use the (-) isomer at the time the invention was made. The motivation is from a well-established principle that one isomer is always more reactive than the corresponding isomer or the racemate. Applicant merely did that which is expected. That is, a search for the more active of the isomers. *In re Adamson*, 125 USPQ 233 (1960).

Applicant's arguments filed 11/16/05 have been fully considered but they are not persuasive. Applicant contends that since the instant compound was allowed in the parent case, methods of using it are allowable. This is generally true but not persuasive because the Office is not in the business of perpetuating its error. Applicant further argues that the instant isomer shows unexpected result vis-à-vis the racemate. This is not persuasive because an isomer is expected to be more active than the racemate or the other isomer. Therefore, applicant's finding is not unexpected.

This is an RCE of applicant's Application No. 10/764,373. All claims are drawn to the same invention claimed in the earlier application and have been finally rejected on the grounds and art of record in this Office action. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taofiq A. Solola, PhD, JD, whose telephone number is (571) 272-0709.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph McKane, can be reached on (571) 272-0699. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.



**TAOFIQ SOLOLA  
PRIMARY EXAMINER**

Group 1626

January 18, 2006